OBSTETRICS & GYNECOLOGY

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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

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Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: Dec 17, 2020
To: "Paul Porter" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-3081

RE: Manuscript Number ONG-20-3081

Accuracy, Clinical Utility and Usability Study of a Wireless Self-Guided Fetal Heart Rate Monitor.

Dear Dr. Porter:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 07, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This study compares the use of a wireless fetal heart rate monitor (HeraBEAT) between 81 clinicians and patients. The baseline FHR of the wireless monitor was compared to standard CTG and found to be between -1.5 and +0.9 bpm. Use was comparable between clinicians and patients. They concluded that the wireless monitor is easy to use for both clinicians and patients and could be used for telehealth consultations.

In order to prove that this wireless monitor is clinically useful it would be important to compare the wireless monitor to the gold standard CTG, not just by baseline, but also by accelerations, short term variability and early, variable and late decels. This would require a length of monitoring longer than 1-5 minutes which was used here. Nonstress tests could be performed by both methods and compared to show that wireless monitoring remotely could replace in person CTG. A 20 min length of monitoring would be long enough to make these comparisons for antenatal patients. Intrapartum tracings could also be compared for the wireless and standard CTG for agreement between these standard tracing parameters.

Eligible patients had to be at least 12 weeks, but it isn't stated what gestational age these patients are when monitored. Does gestational age affect the interpretability of the wireless monitor? It is important to know if prematurity affect interpretation of the wireless monitor.

If home recordings were done 1-21 days after the clinic recordings the length of time between recordings may account for some of the discrepancy. Perhaps the home recordings should be done at a uniform time shortly after the clinic recordings.

Setting the 95% limit of agreement at within 8 bpm seems arbitrary. The agreement between Wireless and CTG recording should be reported, as well as agreement between other tracing parameters such as short term variability, accelerations and type of decelerations.

When wireless and CTG monitoring patients are compared, then BMI and placental position can be examined to look for confounding.

In addition to telehealth consultations, if the wireless monitor gives a truthful tracing that agrees with standard CTG this would allow antenatal testing to be performed from home which would save a great deal of time and money for patients that begin testing as early as 28 weeks and possibly have a frequency of testing of 1-2x/week until delivery.

The Tables 1 & 2 focus on the difference in monitoring between clinicians and patients, but it would be more important to compare wireless monitoring features with standard CTG in order to make a case for monitoring remotely at home.

Reviewer #2: Prospective study evaluating the accuracy and usability of wireless fetal and maternal fetal heart rate monitor

ABSTRACT:
The clinical utility and applicability was NOT evaluated in this study. : Define HBM before using the abbreviation. How were participants selected for each group, randomized or not ? What is the difference between participants who self administered HBM at home vs in the clinic, were those in the clinic helped if they had difficulty with the HBM and if so, were they included?

Introduction:
Line 91: In the US the FHR is NOT often monitored by intermittent auscultation in labor. Paragraph 4 should be moved to the materials and methods

Methods: Overall, should be shortened and simplified.H ow were participants selected for each group?

Delete sentence line 138 - 9 "Potential participants were identified….antenatal clinic"

What were some "conditions on the abdomen" other than rash and why were those with rashes etc excluded?

Results:
How were patients selected, were they randomized to each group

Paragraph2 (line 5) states that five participants contributed a clinic recording and also self recorded. How is this different from the 41 women with simultaneous CTG and HBM monitoring, since these women would have self recorded and had clinic CTG.

Are there a total of 26 women with ONLY home recording?

When evaluating feasibility of a new device, only one encounter per patient should be used, because of the bias introduced by the learning curve of multiple tracings (with anticipated improvement in use).

How did simultaneous HBM and CTG monitoring work, was there interference?

For accuracy it appears that only 41 women (with simultaneous CTG and HBM) should be included. For applicability (ease of use) only one recording (home or HBM without assistance from staff or simultaneous monitoring) should be included.

Are the authors suggesting that this can be used to determine the fetal heart rate but NOT for use for home fetal monitoring as a replacement for NST?

Table 2: Why is maternal HR NA in the home monitoring group? Does the device record the maternal heart rate separately from the FHR?

Why is the total FHR and continuous FHR time NA for clinic HBM

Does the monitor simultaneously display and maternal HR?

Discussion:
Paragraph 1: what is the advantage to HBM over CTG for clinician use?

Paragraph 2: don't repeat results, summarize that there was agreement etc. When you say clinically interpretable, do you mean that a FHR was detected in a "normal" range?

Paragraph 3: this study should not address the need for prenatal visits

Paragraph 6: do the authors recommend a 1 minute HBM to assess variability and accelerations? This study did not address that and this should not be included

Why was the monitoring time period so short? What is the delay between HBM recording and transmission? Is there AI included so that a clinician is alerted real time in the event of abnormal HBM such as fetal tachycardia or bradycardia?

Lines 323 -325: the HBM provides accurate detection of the fetal heart rate, but this study does not address "monitoring". As written, the last paragraph implies that NST can be accurately performed at home

Finally the study is able to conclude that in a small group of women, fetal heart rate can be reliably detected at home in the second and third trimester after short training. Further study with more patients, wide range of BMI and more

patients in the 12 - 24 week range should be evaluated

Reviewer #3: The authors present a manuscript evaluating the accuracy, clinical utility and usability of a wireless, self-guided fetal heart rate monitor. The following items should be addressed:

1. Methods line 140-147 - were women with tachycardia excluded, or were women counseled not to utilize the monitor after exercise? Were the maternal heart rates collected?

2. Methods - did the women have an ultrasound to determine whether or not they had a singleton pregnancy prior to enrollment?

3. Results - line 205-208 are confusing as written. If all women provided home recordings and a recording in the clinic (line 207-208) then what is different for the five who contributed a recording in the clinic and self-recording (line 205)?

4. This journal has an article type labeled "procedures and instruments" - this manuscript should be considered to be submitted under that heading, rather than as original research.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Abstract: Need to include CIs with the various estimates of detect rates or rates of clinically useful tracings. For example detection in 52 of 52 instances has estimate = 100%, but 95% CI = 75%-100%. That is, need to add context to the estimates.

Table 1: Since the column totals were 52, 42 and 32 recordings, the format for n(%) should change to rounding the %s to the nearest integer %, not to 0.1% precision. Also, since there were more recordings than patients, there should be adjustment for repeated measures, in that the recordings cannot be statistically evaluated as independent events. Also, were age, gestational age normal distributions? If not, then should format as median(range or IQR), rather than as mean±SD.

Table 2: Same comments re: precision of %s and independence. Also, were time to first detect, average maternal or fetal HR normal distributions? If not, then should not cite as mean±SD.

Table 4: The subsets by characteristic are relatively small, and therefore there is limited power to discern differences. One cannot generalize from these data the NS findings.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
A. OPT-IN: Yes, please publish my point-by-point response letter.
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2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared

(including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

4. Obstetrics & Gynecology follows the Good Publication Practice (GPP3)* guideline for manuscripts that report results that are supported or sponsored by pharmaceutical, medical device, diagnostics and biotechnology companies. The GPP3 is designed to help individuals and organization maintain ethical and transparent publication practices.

(1) Adherence to the GPP3 guideline should be noted in the cover letter.

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:
(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.
(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.
(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.
(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.
(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).

(4) In the manuscript, a new heading—"Role of the Funding Source"—should be inserted before the Methods and contain a detailed description of the sponsor's role as well as the following language:

"The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication have been disclosed." Authors should only include the above statement if all of it is true, and they should attest to this in the cover letter (see #2, above).

*From Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good publication practice for communicating company-sponsored medical research: GPP3. Ann Intern Med 2015;163:461-4.

5. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

8. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may

infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

9. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com /ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

11. The commercial name (with the generic name in parentheses) may be used once in the body of the manuscript. Use the generic name at each mention thereafter. Commercial names should not be used in the title, précis, or abstract.

12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

13. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

14. Your cover letter contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit. The same goes for the manuscript itself.

15. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

16. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top).

17. Figures

Figure 1: Please provide a high-res version of this figure (tiff, eps, jpeg, etc.). What is the source of this image? If this is from another source, plese provide a letter of permission for print and online use.

Figure 2: Please remove the two tables from the figure and add them as tables to the manuscript. Please upload a high-res version of the image.

Figure 3: Please check your n values (41+42=83 and 52+42=94). Should any exclusion boxes be added? Are any items not mutually exclusive?

Figure 4: The current figure file may be resubmitted as-is with the revision.

Figure 5: The manuscript references a Figure 5, however that is not included on Editorial Manager.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 07, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD, MSPH
Editor-in-Chief

2019 IMPACT FACTOR: 5.524
2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

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Resubmission Cover Letter
29 December 2020

RE: manuscript number ONG-20-3081

Accuracy, Clinical Utility and Usability Study of a Wireless Self-Guided Fetal Heart Rate Monitor.

Dear Dr Rouse,

On behalf of my co-authors, I would like to thank you and your reviewers for the opportunity to resubmit our work. We were very pleased with the quality of the reviews and feel that the critique has significantly improved the manuscript. In particular, the suggestions to present some of the data using medians and interquartile ranges to reflect data distribution (non-normal), and to use only one recording per participant to avoid repeated measures, were very helpful. We have addressed these suggestions throughout the revised manuscript.

The revision has been extensive. The supplied "tracked changes" version is quite busy as there have been changes to nearly every table and result. To help, we have added paragraph and line numbers to the answers in our point by point response below and uploaded a clean version. I hope this will be useful.

I have not copied the original cover letter which outlines our research team and the study's background on the assumption you still have this available to you.

Please find our responses to your review below. Our answers are in blue italics.

We note that your reviewers have expressed an interest in looking at the device to replicate NST's. We agree this is very exciting and we are conducting studies to look at this currently. To help, I have included an image of a recently collected, simultaneous trace (25 min) between the HBM and a Phillip's Avalon CTG in my answer to reviewer 1. I am unsure as to whether your reviewers see all of our responses so, on the assumption they do, I have only included the image in one section of our response letter. You will see that the system does very well in terms of bpm accuracy, as expected, but also clearly mimics the acceleration and variability data obtained from the CTG and needed for NSTs. This image is not a part of this manuscript and is provided only for interest and clarification.

Thank you for your ongoing consideration of our manuscript. I trust that we have answered your questions sufficiently. However, we would be only too pleased to give further explanation on any of the above points.

Kind regards

Dr Paul Porter

Dear Dr. Porter:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it

is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

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In order to prove that this wireless monitor is clinically useful it would be important to compare the wireless monitor to the gold standard CTG, not just by baseline, but also by accelerations, short term variability and early, variable and late decels. This would require a length of monitoring longer than 1-5 minutes which was used here. Nonstress tests could be performed by both methods and compared to show that wireless monitoring remotely could replace in person CTG. A 20 min length of monitoring would be long enough to make these comparisons for antenatal patients. Intrapartum tracings could also be compared for the wireless and standard CTG for agreement between these standard tracing parameters.

Our study aimed to test a wireless fetal heart rate monitor firstly for accuracy (beat to beat comparison with a Gold Standard CTG machine) and secondly to assess the resulting FHR trace for clinical utility and usability in low-risk antenatal care, to replicate intermittent auscultation (of duration 1 minute). The use of fetal heart rate auscultation in this scenario is intended to establish fetal life and reassure the expectant mother. This short auscultation has been an integral part of antenatal care for over 90 years (Sharif & Whittle, 1993). It is recommended in low-risk pregnancies as part of several prenatal care guidelines (including ACOG and RANZCOG) (ACOG, 2017) (Australian Government Department of Health, 2019).

We note in the Discussion section that "Detection of a FHR in the healthy range is the first aim of IA, but recognition of variability is dependent on clinical experience and accelerations are only noted if
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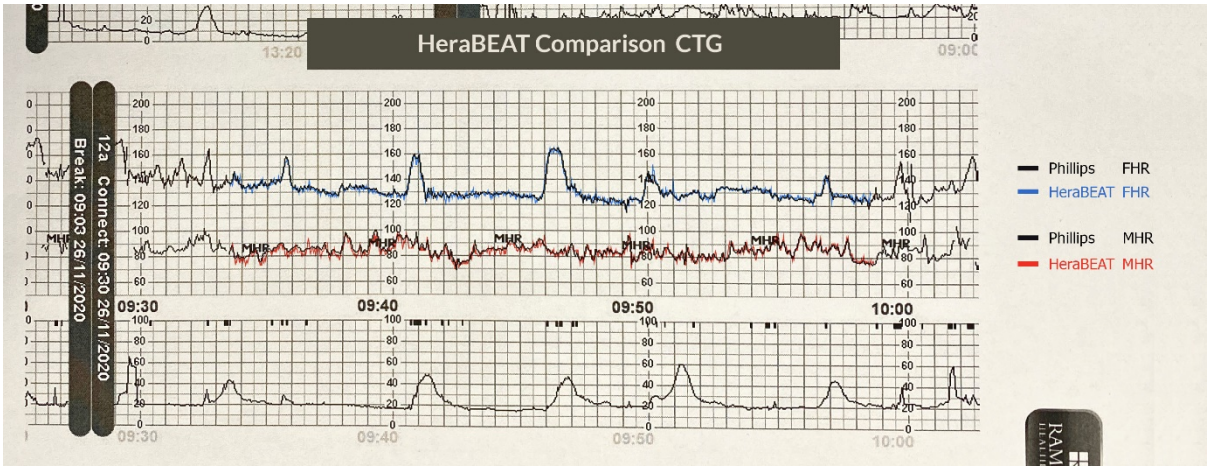
they occur within the 1-minute window." An advantage of the HBM over Doppler, in this situation, is that it produces a readable and archival trace that can be transmitted for later review by clinicians. While our study design was to have at least 1 minute of interpretable recordings, we collected longer FHR tracings (tables 2, 3). The trace provides a true representation of FHR characteristics, allowing an objective, quantifiable interpretation. In our study, the presence of variability and accelerations were scored only if identified, though it is recognized that these may not be present in the duration of trace available. The study was not designed to compare to a formal non-stress test (NST); instead, we have demonstrated that the HBM can accurately and rapidly detect the FHR as per IA. Despite the short duration of trace, we were able to identify accelerations in >73% and variability in 100% of traces. This illustrates that the system has the potential to equal NST from a technical perspective.

We have discussed this further in the study limitations section:
"Our study has several limitations, including the duration of tracings. Based on requirements for IA in antenatal and intrapartum settings, we focused on recording FHRs for at least 1 minute. Our study times significantly exceeded this, but we did cap home recordings to 5 minutes and our findings are not equivalent to nonstress test examinations. In high-risk pregnancies and labor, a 10- to 20-minute CTG recording is recommended to assess baseline FHR, variations, accelerations, and decelerations. Our HBM traces were too short to allow evaluation for decelerations and were not collected during contractions."

The use of a wireless FHR monitor in antepartum surveillance of high-risk pregnancies ("Practice Bulletin No. 145: Antepartum Fetal Surveillance," 2014) as an alternative to CTG-based NST is the goal of a follow-up study currently underway in our hospital. This follow-up study will compare at least 20 minutes of continuous monitoring with HeraBEAT compared to standard CTG including in the intrapartum period. For illustration, please see an example of a 25 minute recording with simultaneous HBM and Phillips Avalon traces superimposed. You will see that the traces (both FHR and MHR) are very close and that accelerations and variability are easily determined to be essentially identical. Please note that this trace is not a part of the current manuscript and is provided only for your information. We will report a large series of longer traces, with accuracy analysis, in 2021.



Eligible patients had to be at least 12 weeks, but it isn't stated what gestational age these patients are when monitored. Does gestational age affect the interpretability of the wireless monitor? It is important to know if prematurity affect interpretation of the wireless monitor.

The HBM has regulatory approval for FHR monitoring from 12 weeks of gestational age.

We have listed the categorical distribution of gestational ages when monitored in Table 1 (by recording site and user). We have added a line in the results stating the range of gestational ages included across the entire study: (Results, para 2):
"The gestation of pregnancy included in the entire study ranged from 12 weeks to 40 weeks, with distribution by user and setting shown in Table 1."

Table 4 shows the relationship between gestational age, placental position and BMI on detecting the FHR, time to the first detection of FHR and FHR trace duration. There were no differences identified in the outcome measures across different gestations (14-26 weeks vs 27-40 weeks) or other maternal characteristics. We have made note that the two participants at 12 weeks gestation were both able to detect the FHR and obtain a 1 minute trace.

If home recordings were done 1-21 days after the clinic recordings the length of time between recordings may account for some of the discrepancy. Perhaps the home recordings should be done at a uniform time shortly after the clinic recordings.

Antenatal clinic visits become more frequent with increasing gestation and vary for clinical and logistical reasons. Accordingly, we anticipate variation in the length of time between the use of HBM by mothers at home and the clinic training visit. By not restricting this length of time in the study we wished to replicate the real-world experience.

Setting the 95% limit of agreement at within 8 bpm seems arbitrary.

The HBM has demonstrated accuracy in laboratory measurement of ± 2bpm, between 50-240 bpm (Appendix 1, HeraBEAT system specification and safety claims). Accuracy comparison studies in clinical settings require a prespecified limit of agreement to be set prior to commencement. We set our 95% limit of agreement at 8 bpm after reference to the paper by Cohen et al. (Accuracy and reliability of fetal heart rate monitoring using maternal abdominal surface electrodes. Acta Obstet Gynecol Scand. 2012; 91: DOI: 10.1111/j.1600-0412.2012.01533), which calculated the limits of agreement of FHR between simultaneous abdominal foetal ECG monitoring and fetal scalp monitoring as between 8.40 bpm and -8.72 bpm. We have added this additional reference to the reference list.

*Further, a paper examining accuracy between FHR detection methods (Mhajna et al. Wireless-remote solution for home fetal and maternal heart rate monitoring. American Journal of Obstetrics & Gynecology MFM-2020. **2**(2): p. 100101) stated: "The limits of agreement for FHR measured by Invu were within 8 bpm of the CTG FHR, a clinically acceptable range to recognize common clinical phenomena including bradycardia, tachycardia, accelerations, and decelerations. Most FHR clinical phenomena are defined as an increase/ decrease of 15 bpm from baseline, which could be detected given a 8 bpm limit of agreement."*

The agreement between Wireless and CTG recording should be reported, as well as agreement between other tracing parameters such as short term variability, accelerations and type of decelerations.

The agreement in FHR between HBM and CTG has been reported (Figure 4) as between -1.6 and +1.0 bpm. After statistical advice, we have changed the reporting measures of the FHR metrics (time to first detect, average MHR, FHR, duration of recording) from means and SD to Median and IQRs as the population was not normally distributed. As short duration of traces recorded precludes the ability to formally report accelerations, decelerations and variability with certainty in any monitoring device, HBM traces were only scored for the presence of these features – a more formal assessment will be undertaken in subsequent studies when CTG traces of longer duration are available for comparison when the presence of these features could reasonably be expected (please see above answer and comparison trace).

When wireless and CTG monitoring patients are compared, then BMI and placental position can be examined to look for confounding.

The accuracy of the device, in bpm, was not affected by BMI or placental position. We have added the following line (results, para 4).
"There was no association between placental position, BMI or gestational age and accuracy"

Appendix 4 gives further details of the characteristics of participants who had any difference>2bpm showing no effect from maternal factors.

Other FHR metric data was evaluated per sub-groups of BMI and placental position (and gestational age) as indicated (Results para 11 and Table 4):
"There was no association between pregnancy variables including BMI, gestation, or recording site; and the time taken to detect a FHR, trace duration, or clinical utility of the HBM trace for the whole population and for pregnancies >28 weeks gestation." "There were no differences when participants < 28 weeks gestation were excluded from the analysis."

In addition to telehealth consultations, if the wireless monitor gives a truthful tracing that agrees with standard CTG this would allow antenatal testing to be performed from home which would save a great deal of time and money for patients that begin testing as early as 28 weeks and possibly have a frequency of testing of 1-2x/week until delivery.

Yes, we agree. The potential application of this technology could be significant. We now know that the device is accurate down to 12 weeks gestation; however, as mentioned above, we need to extend the recording period to show that we have equivalence to NSTs.

The Tables 1 & 2 focus on the difference in monitoring between clinicians and patients, but it would be more important to compare wireless monitoring features with standard CTG in order to make a case for monitoring remotely at home.

We agree that comparing wireless monitoring to standard CTG is important. Our study only used the CTG recordings as a Gold Standard comparator for determining absolute FHR accuracy (bpm) as this is a vital metric to confirm. In this regard, the device performed very well. Ideally, this device could be used to replicate the clinic-based CTGs at home. This is the focus of our current follow-up study comparing longer traces with standard CTG.

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Reviewer #2: Prospective study evaluating the accuracy and usability of wireless fetal and maternal fetal heart rate monitor

ABSTRACT:
The clinical utility and applicability was NOT evaluated in this study.

Our study aimed to evaluate the device's accuracy, examine the FHR metric data for clinical utility equivalent to intermittent auscultation guidelines during clinic visits (antenatal), and to determine if the device was usable by minimally trained pregnant women, at home. Accuracy was evaluated by comparison with Philips Avalon CTG. Usability was assessed using the System Usability Scale questionnaire.

The evaluation of clinical utility was performed by obstetricians according to the following criteria (Methods: pg 7):

"To examine clinical utility, obstetricians reviewed all recordings of over one minute to determine (1) if the FHR was in the normal range, (2) if separate FHRs and MHRs were detected, and (3) if FHR variability or accelerations were detectable during the duration of trace available."

Define HBM before using the abbreviation.

HBM (Heartbeat Monitor) is defined in the Abstract (under Objective) and also in the Introduction (para. 5).

How were participants selected for each group, randomized or not ?

Participants were recruited to the whole study, and each group, as convenience samples. There was no randomization to groups. We have amended the following sentence in the abstract:
"We recruited a convenience sample of women aged 18 years or older with a singleton pregnancy of ≥12 weeks gestation."

The Methods now includes the sentence (para 2, line 1):
"We recruited participants as a convenience sample between July and September 2020 in the obstetrics department of a large metropolitan hospital in Western Australia."

What is the difference between participants who self administered HBM at home vs in the clinic, were those in the clinic helped if they had difficulty with the HBM and if so, were they included?
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Participants (n=42) were shown how to use the device in the clinic by a nurse and then used the device without assistance. Of the 42, 26 took the device home to use again, unassisted and to transfer the trace back to the clinical team for review and interpretation. The participants were not helped to use the monitor.

We have made a minor change to the methods section of the Abstract to clarify:
"Women used the device, unassisted, during a clinic visit with a subset then using it at home."

All women were trained in the use of the device before their first unassisted use as mentioned in methods para 6, line 3 and 4 and para 8 as follows:
"A research nurse showed participants how to use the HBM over a 5-minute training session and asked them to record data in the clinic and at home (self-monitoring). Participants were required to use the monitor unassisted to detect and record data for more than 1 minute."

We have also amended figure 3 to more clearly show the flow of participants through the study by adding participant numbers as a fraction of the cohort and adding the following lines:
*"*Two subjects were included in both the clinician and participant recording arms. †All participants who self-recorded at home were a subset of participants who self-recorded in the clinic."*

Introduction:
Line 91: In the US the FHR is NOT often monitored by intermittent auscultation in labor.
We agree with this comment; however, our study was not designed to evaluate the use of IA during labor; rather, the use of monitoring during routine antenatal care.

In the Discussion, we note that IA is considered appropriate in certain circumstances during labor, however, our study does not address this usage. A detailed exploration of this point is beyond the scope of the current paper.
"The International Federation of Gynecology and Obstetrics *guidelines recommend IA for 1 minute during antenatal care and labor when there is no access to CTGs.[25] In resource-limited settings, it is common for this to be done by direct auscultation, although handheld Doppler devices are preferred because of their accuracy, readable displays, and comfort. In these settings, the HBM would allow even inexperienced operators to record, store, and transmit FHR data accurately. IA is also appropriate and recommended for intrapartum monitoring in low-risk pregnancies, including home births.[25] The HBM could also be used in this setting, but further research is required to see if the device remains accurate during contractions."*

Paragraph 4 should be moved to the materials and methods
Thank you – we have moved the section accordingly.

Methods: Overall, should be shortened and simplified. How were participants selected for each group?

We have clarified that the selection was as a convenience sample, as discussed above.

To aid clarity, we have amended the wording in figure three (participant flow) and specified numbers of the participants per group. We have also stated that all participants who recorded at home had already self-administered in the clinic in the caption to figure 3.
"All participants who self-recorded at home were a subset of participants who self-recorded in the clinic."

A sentence in the statistical methods (describing the confidence intervals) has been removed. The data analysis has been changed from means and SD to medians and IQR's as suggested by the reviewers and Statistician to reflect data distribution (non-Normal).

Delete sentence line 138 - 9 "Potential participants were identified….antenatal clinic"

Thank you, we have removed this sentence.

What were some "conditions on the abdomen" other than rash and why were those with rashes etc excluded?

We have modified the following two sentences in the methods section to provide clarity around this exclusion criteria and to identify the requirement for use of ultrasound gel with the HBM (Methods, para 2 line 4):
"Women who were not able to read English, who had a skin rash or condition on the abdomen that could be irritated by the ultrasound gel, or who had a pacemaker or other implantable electronic devices were excluded from the study."
"The device is activated, coated with ultrasound gel and placed below the umbilicus, as directed by the smartphone interface, to a position-dependent on pregnancy gestation."

Results:
How were patients selected, were they randomized to each group

We have clarified this aspect in the Methods Section – as above.

Paragraph2 (line 5) states that five participants contributed a clinic recording and also self-recorded. How is this different from the 41 women with simultaneous CTG and HBM monitoring, since these women would have self-recorded and had clinic CTG.

We have clarified the groupings with the following sentences:
"Forty-one participants had a recording performed by a clinician. Forty-two participants self-administered the device in the clinic, including two who were also in the clinician-administered group. Twenty-six of the participants who used the device in the clinic took the device home to self-administer."

Please note that as we are now reporting individual participants, and not total recording numbers, here and in figure 3 to align with the statistical analysis changes the number is now "2" rather than "5". We realize that there was an error in our previous submission in that the "5" should have been recordings rather than individuals.

Are there a total of 26 women with ONLY home recording?

No. As it was a requirement for home use that the participant had to have used the device in the clinic, no participants used the device only at home. All participants were shown how to use the device by a nurse. We have clarified this aspect in the Methods (para 6) and in Results (figure 3). In clinical use, we anticipate that the clinic staff will demonstrate how to use the device before providing one for unsupervised home use. We note however that the HBM has approval as an OTC device.

When evaluating feasibility of a new device, only one encounter per patient should be used, because of the bias introduced by the learning curve of multiple tracings (with anticipated improvement in use).

Thank you. We have presented the results by only including the first encounter/recording of each participant resulting in minor changes in several outcomes. We have updated these throughout the text accordingly. Also, the results are now presented as Medians and IQR's following statistical advice. The results are improved in some areas using this approach. For example, there is a shorter time to FHR detection.

The SUS was used by participants in the clinic & at home only once per patient experience. These results were reported independently. Interestingly, no differences were identified between a participant's first or second use as reported in Results: para 10.
"There were no differences in SUS scores between clinic and home monitoring (P=.90, paired t-test)."

How did simultaneous HBM and CTG monitoring work, was there interference?

We have extensive experience with simultaneous FHR recording using standard CTG and HeraBEAT. Since the standard CTG uses a pulsed Doppler system with a 1.0 MHz ultrasound frequency and HeraBEAT uses continuous Doppler system with a 2.0 MHz ultrasound frequency, no interference has been encountered in testing.

Please see the trace provided for reviewer 1 as an example of how the two devices can be used at the same time.

For accuracy it appears that only 41 women (with simultaneous CTG and HBM) should be included.

We have updated the accuracy to only include 41 recordings (one from each participant) in this assessment (Results Para 3 and 4, Figure 4, Bland Altman plot). The results have not changed significantly from the original manuscript. The relevant sections now read.

"We compared the accuracy of the HBM with CTG using simultaneous HBM and CTG recordings from 41 women. Using only the first recording provided by each participant produced 41 recordings totaling

214 time-paired data points, across a FHR range 120-166 bpm. Of the 214 paired measurements, the difference in FHR was ≤2 bpm in 205 (95.8%) and between 2 and 5 bpm in 9 (4.2%).

When the difference between the means of the five time points for each device (n=41) was compared, the 95% limits of agreement were -1.6 bpm to 1.0 bpm, with a mean difference of -0.3 bpm (Figure 4). The intraclass coefficient was 0.99. There was no influence from placental position, BMI or gestational age."

We have kept the section analyzing the whole dataset (i.e. all recordings obtained, para 5 and appendix 5) and show the characteristics of the outliers (>2 bpm) in appendix 4.

For applicability (ease of use) only one recording (home or HBM without assistance from staff or simultaneous monitoring) should be included.

The SUS was used by participants in the clinic & at home only once per patient experience. These results were reported independently. Interestingly, no differences were identified between a participant's first or second use as reported in Results: para 10.
"There were no differences in SUS scores between clinic and home monitoring (P=.90, paired t-test)."

Are the authors suggesting that this can be used to determine the fetal heart rate but NOT for use for home fetal monitoring as a replacement for NST?

In our study, we have only demonstrated that the HBM can accurately and rapidly detect the FHR equivalent to intermittent auscultation rather than NST. Our results show that it can be used for all the antenatal clinical scenarios where IA is appropriate when used in the clinic or at home by women. To detect accelerations/decelerations and variability equivalent to NST's we will simply need to collect longer traces of FHR (as discussed above). This is the focus of ongoing work, including during the intrapartum period. We have collected over 30 traces of more than 20 minutes, however, data collection is still ongoing and we do not wish to report this as interim data yet.

We believe this is covered in the "limitations section" of the Discussion:
"Our study has several limitations, including the duration of tracings. Based on requirements for IA in antenatal and intrapartum settings, we focused on recording FHRs for at least 1 minute. Our study times significantly exceeded this, but we did cap home recordings to 5 minutes, and our findings are not equivalent to nonstress test examinations. In high-risk pregnancies and labor, a 10- to 20-minute CTG recording is recommended to assess baseline FHR, variations, accelerations, and decelerations. Our HBM traces were too short to allow evaluation for decelerations and were not collected during contractions."

Table 2: Why is maternal HR NA in the home monitoring group? Does the device record the maternal heart rate separately from the FHR?

The maternal heart rate (MHR) is detected in every instance that a foetal heartbeat is reported (as two distinct heartrates must be discriminated to enable FHR reporting). If the maternal heartbeat is not

detected the device does not report the FHR even though it may be detected). This is an essential safety aspect of the device eliminating the possibility of confusion in the presence of either maternal tachycardia or fetal bradycardia. Participants sending the traces from home used the device in a "non-clinician mode" (as this is the default setting when the device is supplied to non-clinical users) which does not report the MHR. The following sentence has been included in Table 2 to clarify:
"The mothers using the HBM in the home-setting used the device in the "consumer" mode which detects, but does not report the maternal heart rate."

Why is the total FHR and continuous FHR time NA for clinic HBM?

When participants used the device in the clinic, the recording sessions were stopped when we were confident we had 1 minute of continuous recording as that was all that was required for that section of the study. As we stopped the recordings, it is not helpful to report the somewhat arbitrary total time. We have addressed this truncation as indicated in Methods, para 9:
"When participants used the HBM in the clinic, the recordings were truncated at 1 minute, and total trace times were not reported."

We have added the following sentence to clarify under Tables 2 & 4:
"§Not assessed. When participants used the HBM in the clinic, the recordings were truncated at 1 minute. Total trace times, variability and FHR accelerations were not reported."

Does the monitor simultaneously display and maternal HR?

Yes, HBM uses an optical sensor to distinguish between the FHR and the maternal heart rate to eliminate "crosstalk" in the FHR display. Both the measured average FHR and MHR is displayed to the mother in the app and appears in the FHR trace graph (figure 2).

Discussion:
Paragraph 1: what is the advantage to HBM over CTG for clinician use?

As discussed above the HBM is not intended for use by clinicians as an alternative to CTG based on this study. The current intended use of HBM is self-measurement of FHR by expectant mothers as an alternative to in-clinic or home based antepartum fetal heart rate auscultation. The HBM has clear advantages over handheld Doppler devices currently used for IA as stated in paragraph 6 of the Discussion:
"The HBM has advantages over handheld Doppler devices for IA, including cost, ability to distinguish maternal and fetal heart rates, ease of use for self-administration, data storage, and transmission capabilities."

We do feel that as we collect longer traces and potentially show equivalence with CTG traces the device may be used in more settings including remote monitoring, low resource areas (from where recordings could be transferred for further analysis) and during labour. We wish to examine these possibilities thoroughly in further studies that are currently ongoing.

Paragraph 2: don't repeat results, summarize that there was agreement etc. When you say clinically interpretable, do you mean that a FHR was detected in a "normal" range?

Thank you. We have amended the word "clinically interpretable" throughout the text to "clinical utility" which is defined in Methods, para 10.

In paragraph 2 we have amended the text to:
"FHR traces met the defined clinical utility criteria in all clinician-performed and in 97% of participant-administered recordings."

We have edited the whole paragraph to summarize the findings rather than repeat the results.

Paragraph 3: this study should not address the need for prenatal visits

We anticipate that the major use of this technology will be during antenatal visits, especially those conducted remotely. We have removed the suggestion that the device could be used during intrapartum care usage as it is outside the scope of this study.

Paragraph 6: do the authors recommend a 1 minute HBM to assess variability and accelerations? This study did not address that and this should not be included

No: we identify the limitations of IA (of 1 minute duration) in that variability and accelerations may not be encountered in a trace of this duration.

For our clinical utility analysis we used the total recorded trace as stated in Methods para 9:
"To examine clinical utility, obstetricians reviewed all recordings of over one minute to determine (1) if the FHR was in the normal range, (2) if separate FHRs and MHRs were detected, and (3) if FHR variability or accelerations were detectable during the duration of trace available."

We report that we were able to identify accelerations and variability as an additional analysis point that is of considerable interest considering the relatively short tracing times collected (median duration for clinicians and participants being 6.6 and 4.6 min respectively).

Why was the monitoring time period so short?

The aim of this study was to replicate IA (of at least 1 minute duration) focussing on the ability to detect a FHR in the normal range. The majority of recordings were actually of durations greater than 1 minute (with total trace times of 6.6 (clinic) and 4.6 (home) minutes). This study concentrated on accuracy and on low risk antenatal care use where short examination times are the routine.

What is the delay between HBM recording and transmission?

The measurement trace and FHR metric analysis is immediately transmitted to the clinic dashboard. It is also immediately readable on the smartphone linked to the device for bedside viewing.

Is there AI included so that a clinician is alerted real time in the event of abnormal HBM such as fetal tachycardia or bradycardia?

The current version of HBM doesn't include AI based interpretation. For real time alerts in cases of fetal tachycardia or bradycardia no AI is needed. The manufacturing company (HeraMED, Netanya, ISRAEL) provides a dashboard for remote monitoring management including customizable alerts. The dashboard was not part of this study.

The system gives basic details on a printable pdf derived from the recording including average FHR and MHR using beat-to-beat calculation, duration of FHR trace, duration of search time, and longest continuous FHR segment.

Lines 323 -325: the HBM provides accurate detection of the fetal heart rate, but this study does not address "monitoring". As written, the last paragraph implies that NST can be accurately performed at home

Thank you, we have replaced the words "and clinically relevant monitoring" with "detection" in the last paragraph of the Discussion.

Finally the study is able to conclude that in a small group of women, fetal heart rate can be reliably detected at home in the second and third trimester after short training. Further study with more patients, wide range of BMI and more patients in the 12 - 24 week range should be evaluated

We have added the following statement to the Discussion, noting that we, or others, will need to replicate the findings in a larger patient group:
"We have shown that women are able to use the HBM at home to perform accurate and clinically relevant monitoring of FHR, though replicating the findings in more patients, particularly in the second trimester would be valuable."

We were pleased to see that anterior placental positioning and moderate obesity did not adversely alter our results.

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Reviewer #3: The authors present a manuscript evaluating the accuracy, clinical utility and usability of a wireless, self-guided fetal heart rate monitor. The following items should be addressed:

1. Methods line 140-147 - were women with tachycardia excluded, or were women counseled not to utilize the monitor after exercise? Were the maternal heart rates collected?

Women with tachycardia or post-exercise were not excluded from the study. Maternal heart rates are detected in all cases, as the device will not report the FHR unless a MHR is also detected as a safety
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feature. This eliminates the possibility of confusing maternal and fetal heart rates which may be of clinical significance during episodes of maternal tachycardia or fetal bradycardia.

It is important to note that the study was not designed to detect abnormalities in the FHR but to assess the accuracy and usability of the device. That is, whether the device delivers accurate and useful information that is interpretable by clinicians and is easy to use by women. The accuracy of the HBM was demonstrated across range of FHRs (118 bpm to 170 bpm) as shown in the Bland Altman Plot (Appendix 5) while the maternal heart rates had a median of 91 (IQR 84-97) bpm.

2. Methods - did the women have an ultrasound to determine whether or not they had a singleton pregnancy prior to enrollment?

Participants had a routine, clinical ultrasound performed prior to enrolment during normal clinical care (not related to the study) to detect multiple pregnancy. Ultrasound results were self-reported to recruiting nurses by the participants. We have added a clarifying sentence as follows (methods, para: 2):
"Women aged 18 years or older with a self-reported singleton pregnancy of at least 12 weeks gestation were approached to participate in the study."

3. Results - line 205-208 are confusing as written. If all women provided home recordings and a recording in the clinic (line 207-208) then what is different for the five who contributed a recording in the clinic and self-recording (line 205)?

We have edited this paragraph to improve clarity. Please note that the "5" corresponded to the number of recordings, not participants. As we are now reporting only one recording per participant in this section the actual number of participants that were in both the clinician and self-administration groups is 2. Thus, 41 women were enrolled in the clinician group and 42 women were enrolled in the self-administered group (that included only 2 women who were also in the clinician group). Of the 42 self-administering participants, 26 took the device home to use. The paragraph now reads:
"Forty-one participants had a recording performed by a clinician. Forty-two participants self-administered the device in the clinic, including two who were also in the clinician administered group. Twenty six of the participants who used the device in the clinic took the device home to self-administer."

We have also amended Fig 3 to be clearer in this aspect and added the following to the caption:

*"*Two subjects were included in both the clinician and participant recording arms. †All participants who self-recorded at home were a subset of participants who self-recorded in the clinic."*

4. This journal has an article type labeled "procedures and instruments" - this manuscript should be considered to be submitted under that heading, rather than as original research. *We will leave this for the Editor's consideration. Thank you.*

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STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Abstract: Need to include CIs with the various estimates of detect rates or rates of clinically useful tracings. For example detection in 52 of 52 instances has estimate = 100%, but 95% CI = 75%-100%. That is, need to add context to the estimates.

We have made several changes to the original abstract to account for the following:

1. *Using medians and IQR's rather than means and SD where appropriate.*
2. *Adding actual numbers of participants alongside percentages. For example* "obtaining a continuous trace of >1 minute in 95% (39/41) of occasions"
3. *Added CIs and intraclass coefficient numbers to the accuracy data*
4. *Clarified recruitment as a convenience sample*
5. *Reported accuracy and FHR metrics results only using one (the first) recording of any participant to avoid repeated measures. The accuracy was not adversely affected using this approach.*
6. *Altered wording to comply with the 300 word limit.*

Table 1: Since the column totals were 52, 42 and 32 recordings, the format for n(%) should change to rounding the %s to the nearest integer %, not to 0.1% precision.

Thank you, the requested changes have been made.

Also, since there were more recordings than patients, there should be adjustment for repeated measures, in that the recordings cannot be statistically evaluated as independent events.

Thank you. We have adjusted the manuscript as follows.

We have reanalysed the accuracy and the FHR metric data, as suggested by the reviewers and Statistician, to now report using only the participant's first recording. Now, participant and recording numbers are equal for the accuracy and FHR metric analyses. We were pleased to see this did not materially change the results and improved them in some instances. In particular, as seen in table 2, the time to first detect the FHR was under 2 minutes in 100% of clinician users and 96-98% when used by women. The median time to detect a FHR was 30 seconds for both clinicians and participants.

The accuracy study now uses 41 recordings (205 paired time points). The 95% LOA remain excellent at "-1.6 bpm to 1.0 bpm, with a mean difference of -0.3 bpm"

We still report the whole set of time-paired heart rate data, using all recordings (260 paired points) as we feel this gives relevant information as to the number of individual measures that were > 2 beats per minute different. We report these outliers in Appendix 4 and have moved the Bland Altman plot describing all collected data as individual measures (previously figure 4) to Appendix 5. We feel this will still be of interest to your readers.

SUS scores were already reported as one event per participant, but we note two time points where participants filled in the questionnaires – in the clinic and at home. These two data sets were analyzed

separately and we note that comparing the two sets did not show differences: "There were no differences in SUS scores between clinic and home monitoring (P=.90, paired t-test)."

Also, were age, gestational age normal distributions? If not, then should format as median (range or IQR), rather than as means.
Thank you for this observation. We now report gestational age as Median and IQR. Age is still reported as mean and SD.

Table 2: Same comments re: the precision of %s and independence.
As per our answer to the queries on table 1, we now use only the first recording from each participant in calculating the FHR metric results. The percentage data have been amended to whole integers.

Also, were time to first detect, average maternal or fetal HR normal distributions? If not, then should not cite as mean±SD.
We have amended the table to express the data as median and IQR for the time to first detect the FHR, average maternal and fetal heart rates, continuous FHR trace duration and total FHR trace duration.

Table 4: The subsets by characteristic are relatively small, and therefore there is limited power to discern differences. One cannot generalize from these data the NS findings.
We have altered the reporting in this table to Medians and IQR's from means and SD. We report the results based on single recordings from participants to avoid repeated measures.

By recalculating these results we found the previously reported significant difference between the time it took a clinician and a participant's to detect a FHR has now become insignificant (p=0.08).

We agree that larger numbers of participants will be of benefit. We have added the following statement to the Discussion, noting that we will need to replicate the findings in a larger patient group: "We have shown that women are able to use the HBM at home to perform accurate and clinically relevant monitoring of FHR, though replicating the findings in more patients, particularly in the second trimester would be valuable."

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

A. Opt-in: Yes, please publish our point-by-point response letter.

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

All co-authors confirm that their disclosures are correct.

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

We have added a Data Sharing Box after the references.

4. Obstetrics & Gynecology follows the Good Publication Practice (GPP3)* guideline for manuscripts that report results that are supported or sponsored by pharmaceutical, medical device, diagnostics and biotechnology companies. The GPP3 is designed to help individuals and organization maintain ethical and transparent publication practices.

(1) Adherence to the GPP3 guideline should be noted in the cover letter.

We confirm we adhere to the GPP3 guidelines.

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:
(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.

This is a true statement

(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.

This is a true statement

(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.

This is a true statement

(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.

This is a true statement

(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

This is a true statement

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).

This following been added.
"Funding Sources: *The HeraBEAT devices used were loaned by HeraMED Pty Ltd (HeraMED, Netanya, ISRAEL). The study was supported by PHI Research Group (not-for-profit) which was responsible for Statistician fees and Research Assistants' salaries. Joondalup Health Campus provided infrastructure support, and IT services in-kind to the PHI research group."*

(4) In the manuscript, a new heading—"Role of the Funding Source"—should be inserted before the Methods and contain a detailed description of the sponsor's role as well as the following language:

"The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication have been disclosed." Authors should only include the above statement if all of it is true, and they should attest to this in the cover letter (see #2, above).

We have added the following text to the manuscript.
"Role of the Funding Source.

HeraMED Pty Ltd supplied the HBMs used in the study on loan and supplied media images of the HBM system for inclusion in the manuscript. HeraMED did not have a role in protocol design, data acquisition, or analysis. Data remains the property of the named investigators. The authors had access to relevant aggregated study data and other information (such as study protocol-analytic plan and report-validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research-data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication have been disclosed."

*From Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good publication practice for communicating company-sponsored medical research: GPP3. Ann Intern Med 2015;163:461-4.

5. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

No author is employed by HeraMED Pty Ltd or another pharmaceutical or device company. Several authors and their families have investments in HeraMED (a publicly listed company on the Australian Stock Exchange), which have been fully disclosed.
PP has declared an interest in a group that has offered to introduce the company to healthcare researchers. This company has an investment (shares) in HeraMED. No financial compensation was obtained from this association. It is this group that PP has disclosed as his share/option ownership in the Financial Disclosure section.

We have added an acknowledgement of the author's shareholdings under "financial disclosures", however, we are unsure if this is a duplication given our individual COI submissions.
"DS, JCh are shareholders and option holders of HeraMED Pty Ltd. PP has an interest in a company that holds shares and options of HeraMED Pty Ltd."

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

We believe we comply with these definitions.

7. Because of space limitations, it is important that your revised manuscript adhere to the following

length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.
Word count 5356, excluding references. We have changed the Appendix/supplemental data to digital rather than Print to comply with the 5500 limit.

8. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

These aspects are covered in the acknowledgement section of the manuscript

9. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

Abstract length=300 words

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

Only standard abbreviations have been used.

11. The commercial name (with the generic name in parentheses) may be used once in the body of

the manuscript. Use the generic name at each mention thereafter. Commercial names should not be used in the title, précis, or abstract.

The commercial name of the monitor is the HeraBEAT fetal monitor for which we have used the generic "Heartbeat Monitor (HBM)" throughout the manuscript. We have not used the HeraBEAT name in the title, precis or abstract. We have removed the name from the titles of figures 1 and 2 and replaced "HeraBEAT" with FHR monitoring system.

"HeraBEAT" has been used in the following sections.

1. *Financial disclosures.* "The HeraBEAT devices used in this study were loaned by HeraMED Pty Ltd (HeraMED, Netanya, ISRAEL)."
2. *Funding sources (abstract).* The HeraBEAT devices used in this study were loaned by HeraMED Pty Ltd (HeraMED, Netanya, ISRAEL)."
3. *Manuscript Introduction: "HeraBEAT (HeraMED, Netanya, ISRAEL) is a medical-grade, low-cost, wireless, self-guided, fetal and maternal heartbeat monitor (HBM) designed for self-administration from 12 weeks of gestation."*
4. *Supplementary Files (Appendix 1). "System specification and safety claims." This is a commercial document included for your readers' interest and outlines details of the system that would be too long to have in the manuscript. To include this data, the correct name of the document should be retained.*

12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

We have edited the text accordingly.

13. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

We have taken the advice of your reviewers and Statistician and made several significant changes including:

1. *Reporting medians and IQR's when data is not normally distributed.*
2. *Restricting the analysis to one recording per participant (to avoid repeated measures issues) in the accuracy and FHR metric analyses.*
3. *Altering the P values accordingly (only one change from the original data with the presence of an anterior placenta becoming insignificant.*

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in US dollar amounts.

These analyses are not appropriate for this study. We have referenced a paper that has examined the general cost savings, in percentage terms, from introducing digital tools in the Discussion.
"The cost of US prenatal care may be reduced by 2.5% to 13% by using digital tools during telehealth consultations.[19]"

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

The manuscript has been amended to comply with these requirements.

14. Your cover letter contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit. The same goes for the manuscript itself.

Thank you, we did not make this claim in the text of the manuscript, and due to word count limitations we do not feel that adding it would be valuable. We are aware that this is the first clinical report of the device and a Medline (Ovid search), KEYWORDS: HeraMED, HeraCARE, HeraBEAT, DATE: 2000-current (Dec 2020), LANGUAGES: all, revealed no applicable entries. Repeating the search in ProQuest using the same parameters showed no applicable entries.

15. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

We have edited the tables to conform to these requirements.

16. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.
In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items

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We have reviewed and edited the references.

17. Figures
Figure 1: Please provide a high-res version of this figure (tiff, eps, jpeg, etc.). What is the source of this image? If this is from another source, please provide a letter of permission for print and online use.

We have provided high definition version of this figure and a letter of permission for use. The source of the image is from stock media material provided by HeraMED Pty Ltd.

Figure 2: Please remove the two tables from the figure and add them as tables to the manuscript. Please upload a high-res version of the image.

Figure 2 is a non-editable image. The image of the "table" presented is the pdf output screen/page to the operator and represents the trace positioned alongside and so has not been separated.

Figure 3: Please check your n values (41+42=83 and 52+42=94). Should any exclusion boxes be added? Are any items not mutually exclusive?

The total participants are n=81. Of these 81, 41 had recordings by clinician and 42 had participant recordings. Thus in the second line of figure 3, 41 and 42 do not equal 81 as they are subsets of the total enrolled cohort. We have amended the figure to give numbers as a proportion of the total. That is, "recorded by clinicians n=41/81, "recordings by participants in the clinic n=42/81", "recordings by participants at home n=26/42".

We have also added text to the caption to clarify the recruitment participant flow:
***"Figure 3:** Patient involvement in the study. [*]Two subjects were included in both the clinician and participant recording arms. [†]All participants who self-recorded at home were a subset of participants who self-recorded in the clinic."*

Figure 4: The current figure file may be resubmitted as-is with the revision.

We have removed figure 4 (Bland Altman plot using all time-paired points) after considering the reviewers request to only use one recording per patient and placed it as Appendix 5. We have summarised this data in the text as follows (Results, para 5).
"Eleven of the 41 participants were recorded twice giving 52 recordings and 260 time-paired data points for comparison. When all individual time-paired data points were evaluated, the 95% limits of agreement between measurement devices were -2.982 bpm and 2.397 bpm, with a mean difference

of -0.292 bpm (Appendix 5). The intraclass correlation coefficient was 0.99. Characteristics of participants with a difference of >2 bpm between HBM and CTG at any given time point are shown in Appendix 4."

Figure 5: The manuscript references a Figure 5, however that is not included on Editorial Manager. *There is now no figure 5. Instead, figure 4 is the Bland Altman plot entitled as follows*

"Figure 4: Bland-Altman plot showing comparable accuracy between the fetal heartbeat monitor and the Cadiotocograph. Difference in mean fetal heart rates over five time points (n=41)."

This analysis uses only one recording per participant.
